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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,034	09/22/2003	Rainer Bosse	33544/US	1433
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			EXAMINER	
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			07/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/668,034	Applicant(s) BOSSE ET AL.	
	Examiner Christopher D. Koharski	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-24 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5-22 and 24 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 4/13/2007 in which claims 2 and 18 were amended, with new claims 23-24 added. Currently claims 1-2 and 5-24 are pending for examination in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-6, 18-21 and 24 rejected under 35 U.S.C. 102(b) as being anticipated by Nathan et al. (5,384,255). Nathan et al. discloses a needle cover assembly for syringes.

Regarding claims 1, 5-6, 18-21 and 24, Nathan et al. discloses a cannula cover for an injector (Figure 10) that can be axially retracted to expose a cannula (110) with a closed front and a sealing device (166) that is coupled to the interior of the cannula cover and opens via radial movement of the sealing device made up of two tongues from the center of the cannula passage opening. Wherein the sealing tongues move away from each other and are fixed at the rear portion of the cannula cover and are moveable via a slaving means (174) by the cover's rotation.

Claim Rejections - 35 USC § 102

Claims 1, 7-11, 12, 15-18, 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Castillo et al. (5,336,199). Castillo et al. discloses a medical needle and needle sheath assembly.

Regarding claims 1, 7-11, 12, 15-18, 22 and 24, Castillo et al. discloses a cannula cover (Figures 3-6) that can be axially retracted prior to use to expose a cannula (14) with a substantially closed facing front wherein a sealing device (26) is coupled to the interior of the device that can expose the cannula opening via radial retraction of the sealing device (Figure 4), wherein the sealing device (or strip) comprises a covering flap (26) that can be slid away in a longitudinal guide. A spring element is provided (40) to bias the cover and a spring (52) element to bias the opening member.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C 103(a) as being unpatentable over Nathan et al. (or Castillo et al.) in view of Vaillancourt (5,591,138). Nathan et al. (or Castillo et al.) meets the claim limitations as described above except for a rotational latch.

However, Vaillancourt teaches a protected needle assembly.

Regarding claim 2, Vaillancourt teaches a needle assembly with a latch 21-24) that control rotational movement (Figures 1-5).

At the time of the invention, it would have been obvious to add the latch of Vaillancourt to the system of Nathan et al. (or Castillo et al.) because the addition of latch allows for additional cover movement control. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Vaillancourt.

Claim Rejections - 35 USC § 103

Claims 13-14 are rejected under 35 U.S.C 103(a) as being unpatentable over Nathan et al. (or Castillo et al.) in view of Foster (6,217,559). Nathan et al. (or Castillo et al.) meets the claim limitations as described above except rotational threading.

However, Foster teaches an automatic safety syringe.

Regarding claims 13-14, Foster teaches a threaded insert (50) that is coupled to the cover and controls rotation movement (Figures 1-4, col 2, ln 1-69).

At the time of the invention, it would have been obvious to add the threaded element to the system of Nathan et al. (or Castillo et al.) because the addition of the

threaded element allows for controlled axial movement. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Foster.

Allowable Subject Matter

Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 4/13/2007 have been fully considered but they are not persuasive. Applicant's Representative argues that the Nathan and Castillo references do not disclose a "cannula cover for an injector" and "a sealing device that exposes a cannula... closure moving an radial movement away form the center...".

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the Nathan reference discloses a cannula (110) cover assembly (Figure 10) wherein the cover elements (160, 162) expose a cannula passage, regarding the Castillo reference the blocker elements (26) sealing end (50) is moved away form the center of the device towards the spring element (52) to provide a passage opening in the cannula cover member.

Additionally, Examiner also asserts that several other claims are rejected by the Castillo reference and Applicant's Representative only makes arguments to claimed elements in claim 18, therefore independent claim 1 still reads on the reference since no arguments are present in this filed response.

In response to applicant's arguments against the combination of references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Therefore the prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

6/21/07



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